DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 23, 2015

Saset (Chengdu) Inc.
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai 200120
CHINA

Re: K150002
Trade/Device Name: iNSIGHT Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 15, 2015
Received: June 17, 2015

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150002

Device Name
Trade Name: iNSIGHT Color Doppler Ultrasound System
Models of iNSIGHT Color Doppler Ultrasound System: iNSIGHT 37C, iNSIGHT 25C, iNSIGHT 35R, iNSIGHT 23R, iNSIGHT 11R, iNSIGHT 10B and iMago c21; Models of Probes: SH3C50, SH3P30, SH4DC54, SH6E47 and SH7L38

Indications for Use *(Describe)*
The iNSIGHT Color DopplerUltrasound System is intended for visualization of ultrasound of internal organs, for medical diagnostic purposes only. The main applications are: General radiology, Abdominal (excluding fetal Doppler), Vascular, OB/GYN, Urology, Breast, Superficial Organ (Small Parts), Musculoskeletal, and Cardiology. Each application includes a set of exams, including the specific measurements, reports, pictograms, annotations and system presets.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Diagnostic Ultrasound Indications for Use Format

System: iNSIGHT Color Doppler Ultrasound System

Transducer: **SH3C50** Convex Array Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	BMDC	1,2,3
	Abdominal	N	N	N		N	BMDC	1,2,3
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	BMDC	1,2,3
	Small Organ(Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

1. Tissue Harmonic Imaging (THI)
2. Spatial Compounding Imaging
3. Freehand 3D imaging
4. Panoramic B and Color mode
5. STIC
6. Strain image
7. ARFI strain image
8. Tissue Doppler Imaging (TDI)
9. 4D Imaging

Diagnostic Ultrasound Indications for Use Format

System: iNSIGHT Color Doppler Ultrasound System

Transducer: **SH3P30** Phased Array Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ(Specify)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N		N	BMDC	1
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N	N	N	BMDC	1,5,8
	Cardiac Pediatric	N	N	N	N	N	BMDC	1,5,8
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

1. Tissue Harmonic Imaging (THI)
2. Spatial Compounding Imaging
3. Freehand 3D imaging
4. Panoramic B and Color mode
5. STIC
6. Strain image
7. ARFI strain image
8. Tissue Doppler Imaging (TDI)
9. 4D Imaging

Diagnostic Ultrasound Indications for Use Format

System: iNSIGHT Color Doppler Ultrasound System

Transducer: **SH4DC54** Volume Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	BMDC	1,2,3,9
	Abdominal	N	N	N		N	BMDC	1,2,3,9
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ(Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

1. Tissue Harmonic Imaging (THI)
2. Spatial Compounding Imaging
3. Freehand 3D imaging
4. Panoramic B and Color mode
5. STIC
6. Strain image
7. ARFI strain image
8. Tissue Doppler Imaging (TDI)
9. 4D Imaging

Diagnostic Ultrasound Indications for Use Format

System: iNSIGHT Color Doppler Ultrasound System

Transducer: **SH6E47** Cavity Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ(Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	BMDC	1,2
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	N	N	N		N	BMDC	1,2
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

1. Tissue Harmonic Imaging (THI)
2. Spatial Compounding Imaging
3. Freehand 3D imaging
4. Panoramic B and Color mode
5. STIC
6. Strain image
7. ARFI strain image
8. Tissue Doppler Imaging (TDI)
9. 4D Imaging

Diagnostic Ultrasound Indications for Use Format

System: iNSIGHT Color Doppler Ultrasound System

Transducer: **SH7L38** Linear Array Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	BMDC	1,2,3,4,6,7
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	BMDC	1,2,3,4,6,7
	Small Organ(Specify)	N	N	N		N	BMDC	1,2,3,4,6,7
	Neonatal Cephalic							
	Adult Cephalic	N	N	N		N	BMDC	1,2,3,4,6,7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	BMDC	1,2,3,4,6,7
	Musculo-skeletal (Superficial)	N	N	N		N	BMDC	1,2,3,4,6,7
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	BMDC	1,2,3,4,6,7
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

1. Tissue Harmonic Imaging (THI)
2. Spatial Compounding Imaging
3. Freehand 3D imaging
4. Panoramic B and Color mode
5. STIC
6. Strain image
7. ARFI strain image
8. Tissue Doppler Imaging (TDI)
9. 4D Imaging

Tab #7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K150002

1. Date of Preparation: 12/19/2014

2. Sponsor Identification

Saset (Chengdu) Inc.
A-601, Huoju Building, #16 Chuangye RD
B Hi-Tech Avenue, Hi-Tech Zone
Chengdu, Sichuan, 610041, China

Establishment Registration Number: 3007751490

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Lee Fu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: iNSIGHT Color Doppler Ultrasound System
Common Name: Diagnostic Ultrasound System and Transducers

Models of iNSIGHT Color Doppler Ultrasound System: iNSIGHT 37C, iNSIGHT 25C, iNSIGHT 35R, iNSIGHT 23R, iNSIGHT 11R, iNSIGHT 10B and iMago c21

Models of Probes: SH3C50, SH3P30, SH4DC54, SH6E47 and SH7L38

Regulatory Information
Classification Name: Ultrasound Pulsed Doppler Imaging System;
Classification: II;
Product Code: IYN;
Regulation Number: 21 CFR 892.1550;
Review Panel: Radiology;

Classification Name: Ultrasonic Pulsed Echo Imaging System;
Classification: II;
Product Code: IYO;
Regulation Number: 21 CFR 892.1560;
Review Panel: Radiology;

Classification Name: Diagnostic Ultrasound Transducer;
Classification: II;
Product Code: ITX;
Regulation Number: 21 CFR 892.1570;
Review Panel: Radiology;

Intended Use Statement:
The iNSIGHT Color Doppler Ultrasound System is intended for visualization of ultrasound of internal organs, for medical diagnostic purposes only. The main applications are: General radiology, Abdominal (excluding fetal Doppler), Vascular, OB/GYN, Urology, Breast, Superficial Organ (Small Parts), Musculoskeletal, and Cardiology. Each application includes a set of exams, including the specific measurements, reports, pictograms, annotations and system presets.

Device Description

The iNSIGHT Color Doppler Ultrasound Systems are integrated preprogrammed color ultrasound imaging system, capable of producing a resolution intended for clinical diagnostic imaging applications. Their basic function is to acquire ultrasound signal and display the images in the following imaging operations: B, M, PW, CW, CDI, PDI, DPDI, TDI, MC and THI imaging mode, Spatial Compounding Imaging, Panoramic B and Color mode, Freehand 3D, 4D Imaging, Strain imaging, ARFI Elasticity Imaging.

5. Identification of Predicate Device

510(k) Number: K090059
Product Name: iMago c21 Diagnostic Ultrasound System
Model Name: iMago c21

510(k) Number: K130881
Product Name: Acuson S2000 and S3000 Diagnostic Ultrasound Systems
Model Name: Acuson S2000

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2005 + CORR. 1: 2006 + CORR. 2:2007 + AM 1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-2-37: 2007 Medical electrical equipment - Part2 -37 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
- NEMA UD 2-2004 (R2009) Acoustic output measurement standard for diagnostic ultrasound equipment
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity;
- ISO 10993-10:2010, Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization;

Discussion about the testing of strain and elasticity quantitative measurements:

The bench testing for the features providing strain and elasticity quantitative has been conducted to show that the accuracy of the strain and elasticity imaging of the proposed device; the result has been analyzed that they are accepted for clinical use.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device K090059	Predicate Device K130881
Product Code	IYN, IYO and ITX	IYN, IYO and ITX	IYN/ IYO/ ITX/OBJ
Intended Use	The iNSIGHT Color Diagnostic Ultrasound System is intended for visualization of ultrasound of internal organs, for medical diagnostic purposes only. The main applications are: General radiology, Abdominal (excluding fetal Doppler), Vascular, OB/GYN, Urology, Breast, Superficial Organ (Small Parts), Musculoskeletal, and Cardiology. Each application includes a set of exams, including the specific measurements, reports, pictograms, annotations and system presets.	The iMago c21 medical ultrasound system is intended for visualization of ultrasound of internal organs, for medical diagnostic purposes only. The main applications are: General radiology, Abdominal (excluding fetal Doppler), Vascular, OB/GYN, Urology, Breast, Superficial Organ (Small Parts), Musculoskeletal, and Cardiology. Each application includes a set of exams, including the specific measurements, reports, pictograms, annotations and system presets.	The S2000 and S3000 ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral vascular applications. The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information that provide information to the clinician that may be used adjunctively with other clinical diagnosis purposes. The arterial health package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the “ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk; A

				consensus Statement from the Amerian Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging"
Configuration		Color Doppler Ultrasound System	Color Doppler Ultrasound System	Color Doppler Ultrasound System
		Probes	Probes	Probes
		/	/	Ultrasound Catheter
Acoustic Track		Track 1	Track 1	Track 3
Biocompatibility	cytotoxicity	ISO 10993-5	ISO 10993-5	ISO 10993-5
	sensitization	ISO 10993-10	ISO 10993-10	ISO 10993-10
	irritation	ISO 10993-10	ISO 10993-10	ISO 10993-10
Electrical Safety		IEC 60601-1	IEC 60601-1	IEC 60601-1
EMC		IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2
Particular Performance		IEC 60601-2-37	IEC 60601-2-37	IEC 60601-2-37

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.